Technical Screen

Admin No.: 83614-1	**Product name**: DETSAN24 (Alt Brand Name: Byotrol 24 (tested))
Submission #: 1089516	**E-Sub #:** 78525
Action Code: 00382273	**Registrant:** BYOTROL, INC.
Reviewer's name: Cesar E. Cordero	**Risk Manager:** Karen Leavy/Kathryn Montague (RMB 1/PM31)
Completion due date: September 26, 2022	**Completion Date:** September 26, 2022

Formulation type: Liquid []; Towelettes []; Spray [X]; Solid []; Textile[]; Aerosol []; Other_____

Sterilant: []	Disinfectant: [X]	FC Sanitizer: []	NF Sanitizer [X]	TB: [ ]	Fungicidal: [X]	Virucide: [X]

MRID(s): 51971301, 51971302, 51971303 and 51971304 (Efficacy data) and 51971305 (Efficacy discussion volume describing the rationale for using Human Coronavirus as a predictor for SARS-CoV-2 efficacy)

PC Code(s)	Active Ingredient Names	% wt (label)	%LCL
069149	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride (Lonza Bardac 2280 (80%)) (CAS# 7173-51-5)	0.324%	0.2910%
069175	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1% C18) (Acticide BAC 50-F (50%) OR Maquat LC12S – 50% (CAS# 68391-01-5))	0.215%	0.1935%
	Total Quat	0.539%	0.4845% (Acceptable 0.4942%)
111801	Poly (hexamethylene biguanide) hydrochloride (PHMB) (CAS# 32289-58-0)	0.539%	0.4851% (Acceptable 0.4948%)

Label Claims: Broad-spectrum/Hospital (bactericide, virucide, fungicide), Non-food contact sanitizer, residual self-sanitizer, Mildewstat, on hard, non-porous surfaces.

Product Lot(s)	Tested Concentration(s) (w/w)				Tested at LCL
	Quat		PHMB		
	% in CoA	Tested*	CoA	Tested*	
20302 0001ACA	0.518%	0.4840 – 0.4845	0.5146%	0.4809 – 0.4816	Yes [X]* No []
20303 0001ACA	0.520%	0.4755 – 0.4756	0.5304%	0.4850 – 0.4851	Yes [X]* No []
20304 0001ACA	0.516%	0.4719 – 0.4789	0.5227%	0.4780 – 0.4851	Yes [X]* No []

Tested: **RTU** [X] **Diluted** []	**Tested Dilution Rate:** *All lots were diluted to a testing concentration below LCL. See tables below for the dilutions used before testing.
Certificate of Analysis: Yes [X] No []	**Performed by testing Lab:** Yes [X] No []

Test Lab: Efficacy by Element, Analytical Lab Group-Midwest; CoAs by Ecolab Schuman Campus

Comments: The registrant submitted 4 efficacy studies (51971301 - 51971304) to support a label amendment to add residual disinfection claims against bacteria and viruses on hard, non-porous surfaces and reduce the contact time for SARS-CoV-2 claims. The registrant also submitted MRID 51971305 where they provide their rationale for using Human Coronavirus as a predictor for SARS-CoV-2 efficacy.

- Product has **failed**** the technical screen.
  - The submitted residual disinfection studies against viruses (MRID 51971303 and 51971304) are not acceptable because they should have been conducted against the

"hardest-to-kill" virus on the label per the agency's "Interim Guidance - Review for Products Adding Residual Efficacy Claims". In this case the "hardest-to-kill" virus on the label appears to be Norovirus (small, non-enveloped virus). These studies will not be reviewed under the full efficacy review.

- In addition, it appears that for one of the active ingredients (Quat), the most conservative dilution (e.g., lowest of product and highest of diluent) was **not** used and thus the data is not acceptable. For the Quat active ingredient, see table below, the dilution for Lot 20303 0001AC (93.17g substance + 6.83g diluent) should have been used instead of that of Lot 20302 0001ACA (93.53g substance + 6.47g diluent).
  - **The registrant may provide a justification/clarification for this discrepancy that could result in MRID 51971302 (bactericidal residual disinfection) being acceptable for full efficacy review.
- **MRID appears to be acceptable and could continue to the full efficacy review under this submission if the registrant decides to proceed.

Notes:

- MRID 51971305 would not support a SARS CoV-2 label claim. To have a SARS-CoV-2 claim full efficacy data against the virus should be submitted for review. Testing against Human Coronavirus can be used to add the product to EPA List N. The agency is not allowing surrogates for this virus as it is readily available and can be readily tested. The few surrogates the agency currently allows are due to difficulties in acquiring and/or propagating the organism as well as danger/risks associated with conducting efficacy testing (e.g., BSL2 laboratory needed).

Dilution procedure for efficacy testing (or equivalent dilution):

MRID	Batch	Active Ingredient	%LCL from CSF	%AI from CoA	Test Substance Amount (g)	Diluent** Amount (g)	% AI
51971301	20302 0001ACA	Quat	0.4845	0.518	--	--	--
		PHMB	0.4851	0.5146	--	--	--
	20303 0001ACA	Quat	0.4845	0.520	--	--	--
		PHMB	0.4851	0.5304	--	--	--
	20304 0001ACA	Quat	0.4845	0.516	--	--	--
		PHMB	0.4851	0.5227	--	--	--
51971302	20302 0001ACA	**Quat**	**0.4845**	**0.518**	**93.53**	**6.47**	**0.4845**
		PHMB	0.4851	0.5146	94.27	5.73	0.4851
	20303 0001ACA	Quat	0.4845	0.520	**93.17**	**6.83**	0.4845
		PHMB	**0.4851**	**0.5304**	**91.45**	**8.55**	**0.4851**
	20304 0001ACA	Quat	0.4845	0.516	93.89	6.11	0.4845
		PHMB	**0.4851**	**0.5227**	**92.80**	**7.20**	**0.4851**
51971303	20302 0001ACA	**Quat**	**0.4845**	**0.518**	**93.53**	**6.47**	**0.4845**
		PHMB	0.4851	0.5146	94.27	5.73	0.4851
	20303 0001ACA	Quat	0.4845	0.520	**93.17**	**6.83**	0.4845
		PHMB	**0.4851**	**0.5304**	**91.45**	**8.55**	**0.4851**
51971304	20302 0001ACA	**Quat**	**0.4845**	**0.518**	**93.53**	**6.47**	**0.4845**
		PHMB	0.4851	0.5146	94.27	5.73	0.4851
	20303 0001ACA	Quat	0.4845	0.520	**93.17**	**6.83**	0.4845
		PHMB	**0.4851**	**0.5304**	**91.45**	**8.55**	**0.4851**

As indicated in the study reports the dilutions in bold were used for efficacy testing (MRIDs 51971302 – 51971304).

**Diluent was sterile deionized water for MRID 51971301 and "lab purified water" for MRIDs 51971302 – 51971304.

ACTUAL TEST SUBSTANCE USE-SOLUTION PREPARATION

Each batch of test substance was diluted as follows to achieve a concentration at or below the LCL.

MRID 51971301

Test System	Date	Batch	Amount of Test Substance	Amount of Diluent	Active Ingredients	%Tested AI Concentrations*
SARS-Related Coronavirus 2	--	20302 0001ACA	187.06 g	12.94 g	Quat	0.4845
					PHMB	0.4813
					Quat	0.4756

(BEI Resources NR-52281).		20303 0001ACA	182.91 g	17.09 g	PHMB	0.4851
		20304 0001ACA	182.91 g	17.09 g	Quat	0.4719
					PHMB	0.4780

MRID 51971302

Test System	Date	Batch	Amount of Test Substance	Amount of Diluent	Active Ingredients	%Tested Concentration*
Staphylococcus aureus (ATCC 6538)	09/20/21	20302 0001ACA	93.52 g	6.56 g	Quat	0.4840
					PHMB	0.4809
		20303 0001ACA	91.48 g	8.55 g	Quat	0.4756
					PHMB	0.4851
		20304 0001ACA	92.82 g	7.20 g	Quat	0.4789
					PHMB	0.4851
Pseudomonas aeruginosa (ATCC 15442)	09/31/21	20302 0001ACA	93.46 g	6.41 g	Quat	0.4848
					PHMB	0.4816
		20303 0001ACA	91.50 g	8.56 g	Quat	0.4755
					PHMB	0.4850
		20304 0001ACA	92.80 g	7.22 g	Quat	0.4788
					PHMB	0.4850

MRID 51971303

Test System	Date	Batch	Amount of Test Substance	Amount of Diluent	Active Ingredients	%Tested AI Concentrations*
Human coronavirus 229E (ATCC VR-740).	11/08/21	20302 0001ACA	93.51g	6.49 g	Quat	0.4844
					PHMB	0.4812
		20303 0001ACA	91.45 g	8.56 g	Quat	0.4755
					PHMB	0.4850

MRID 51971304

Test System	Date	Batch	Amount of Test Substance	Amount of Diluent	Active Ingredients	%Tested AI Concentrations*
Influenza A virus (H1N1) (ATCC VR-1469).	10/20/21	20302 0001ACA	93.53 g	6.49 g	Quat	0.4844
					PHMB	0.4812
		20303 0001ACA	91.45 g	8.55 g	Quat	0.4755
					PHMB	0.4851